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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,344	11/23/2001	George Jackowski	2132.096	5805
21917	7590	03/07/2007	EXAMINER	
MCHALE & SLAVIN, P.A. 2855 PGA BLVD PALM BEACH GARDENS, FL 33410			CHERNYSHEV, OLGA N	
			ART UNIT	PAPER NUMBER
			1649	
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
2 MONTHS	03/07/2007	PAPER		

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/993,344

Filing Date: November 23, 2001

Appellant(s): JACKOWSKI ET AL.

Ferris H. Lander
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed January 22, 2007 appealing from the Office action
mailed September 20, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

US Application 09/991,796, "Fibronectin biopolymer marker predictive of Type II diabetes", appeal brief filed 12/2006;

US Application 09/994,909, "Complement C3 precursor biopolymer markers related to Alzheimer's disease", appeal brief filed 12/2006;

US Application 09/991,799, "Plasma protease C1 inhibitor biopolymer marker indicative of Alzheimer's disease", appeal brief filed 01/2007.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Clark et al., 1993, Arch. Neurology, Vol.50, pp.1164-72;

Motter et al., 1995, Annals of Neurology, Vol.38, No. 4, pp.643-7.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility or a well established utility.

Claim 1 is drawn to a biopolymer marker peptide consisting of amino acid residues 2-18 of SEQ ID NO: 1 which evidences a link to Alzheimer's disease. The instant specification presents the following definition of the term "biopolymer marker": "the term "biopolymer markers indicative or predictive of a disease state" is interpreted to mean that a biopolymer marker which is strongly present in a normal individual, but is down-regulated in disease is predictive of said disease; while alternatively, a biopolymer marker which is strongly present in a disease state, but is down-regulated in normal individuals, is indicative of said disease state. Biopolymer markers which are present in both disease and normal states are indicative/predictive based upon their relative strengths in disease vs. normal, along with the observation regarding when their signal strengthens/weakens relative to disease manifestation or progression" (p. 11).

At pp. 29-31, the specification explains the significance of identifying a plurality of disease specific marker sequences associated with Syndrome-X: "Syndrome-X is a multifunctional syndrome, which occurs frequently in the general population. [...] This disease is characterized by the clustering of insulin resistance and hyperinsulinemia, and is often associated with dislipidemia [...], hypertension, abdominal (visceral) obesity, glucose intolerance or noninsulin-dependent diabetes mellitus and an increased risk of cardiovascular events. [...] A patient who begins the Syndrome X continuum risks spiraling into a maze of increasingly deadly diseases. The next stages of the Syndrome X continuum lead to overt diabetes, kidney failure, and heart failure, with the possibility of stroke and heart attack at any time. Syndrome X is a dangerous continuum, and preventive medicine is the best defense". The specification further contemplates obtaining samples from a patient and monitoring specific biopolymer markers to assess a Syndrome X disease state as well as to develop methods and means to treat Syndrome X (pp. 32-35). Alzheimer's disease is described within the context of the Syndrome X diseases (p. 27).

The specification discloses a protocol of obtaining biopolymer markers at pp. 25-26 and 40-46. Specifically, a protein content of a sample obtained from a subject is (1) separated by gel electrophoresis, (2) a band of interest is selected based on visual observation of difference of darkness/lightness of the band as compared to other bands, excised and purified from the gel, (3) protein content of the band is subjected to "[T]ryptic digestion of each band" (p. 25), and (4) the fragments, which are the results of artificial proteolytic digestion of the proteins within the band, are identified by means of mass spectrography. At p. 46, it is stated that as a result of these procedures, two fragments of apolipoprotein J precursor protein, which are fragments 2-18 of

SEQ ID NO: 1 and 2-13 of SEQ ID NO: 3, and also a fragment of sulfated glycoprotein-2, which is SEQ ID NO: 2, residues 2-18, “related to Alzheimer’s disease were found”. It is not disclosed if the fragments are present, not present or present at different levels in samples identified as obtained from AD patients.

A specification can meet the legal requirements of utility and enablement for a new peptide as long as the specification discloses at least one credible, specific and substantial asserted utility for the new peptide, or a well-established utility for the claimed peptide would be readily apparent to the skilled artisan. A hypothetical example may serve to clarify. For example, a hypothetical specification discloses that a claimed peptide is expressed in colon cancer and not expressed in healthy colon tissue. The hypothetical specification does not disclose the biological activity of the polypeptide encoded by the polynucleotide. The claimed peptide in the hypothetical example would not be rejected under 35 U.S.C. §§ 101 and 112, first paragraph, as it has utility and is enabled as a colon cancer marker. Alternatively, a hypothetical specification could disclose that a claimed peptide is expressed at specific altered levels in colon cancer as compared to healthy colon tissue. One skilled in the art would immediately recognize that the peptide in hypothetical example would be useful as a colon cancer marker. However, such is not the fact pattern here.

The instant specification discloses a peptide 2-18 of SEQ ID NO: 1, which is an artificially produced fragment of a larger naturally occurring molecule, which is stated to be related to Alzheimer’s disease. First, there is no evidence of record that this peptide 2-18 of SEQ ID NO: 1 is a naturally occurring fragment that can be easily detected in a sample as a diagnostic measure. In order to obtain the peptide 2-18 of SEQ ID NO: 1, proteins must be first cleaved by

trypsin, which is a proteolytic digestive enzyme. The specification provides no evidence or sound scientific reasoning to support a conclusion that the results of enzymatic digestion of the different protein samples by trypsin would predictably lead to the production of the peptide 2-18 of SEQ ID NO: 1.

Second, the instant specification fails to explain the relationship between a peptide 2-18 of SEQ ID NO: 1 and Alzheimer's disease. It is stated on page 46 that, "Figures 1, 3 and 5 are photographs of a gel which is indicative of the presence/absence of the marker in disease vs. control and, in cases where the marker is always present, the relative strength, e.g. the up or down regulation of the marker relative to categorization of disease state is deduced". While it is not necessary that Applicant understands or discloses the mechanism by which the invention functions, in this case, in the absence of such an understanding the following questions must be answered. Is it "the up or down regulation of the marker relative to categorization of disease state"? Or is "the presence/absence" of the peptide 2-18 of SEQ ID NO: 1 indicative of a disease?

Also, it is well known in the art that a diagnosis of Alzheimer's disease is only definitive at postmortem examination or at brain biopsy (see Clark et al., 1993, and Motter et al, 1995, for example). The instant specification, as originally filed, fails to disclose any specific information regarding the data presented in Figures 1-6, such as, description of the samples, their type, size, representative number, as well as description of the subjects, such as how the Alzheimer's diagnosis was made and confirmed, which constitutes a major critical issue when it comes to evaluation of experimental data. Without this important information, the worker of skill in the art

would have to engage in significant further research to experiment, discover and define “the link” between the peptide of SEQ ID NO: 1 and AD.

Applicant’s invention is predicated on the finding that serum samples of possible AD after being processed/digested by enzymes, contain or lack a peptide 2-18 of SEQ ID NO: 1. Applicant further extrapolates this result into an assertion that SEQ ID NO: 1 can be used as a biopolymer marker, “which evidences a link to Alzheimer’s disease”. Accordingly, it would appear that Applicant provides a single finding (the finding), and then presents an invitation to experiment and determine if a peptide 2-18 of SEQ ID NO: 1 could be used as a marker for Alzheimer’s disease. Such experimentation would include determination if a peptide 2-18 of SEQ ID NO: 1 is absent or present or present at particular levels in specific tissue or body fluid samples of persons suffering from Alzheimer’s disease or who are at risk of developing AD *versus* other forms of neurological conditions and normal individuals.

The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which the court expressed the opinion that all chemical compounds are “useful” as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed “real world” utility. The court held that:

“The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility”, “[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field”, and “a patent is not a hunting license”, “[i]t is not a reward for the search, but compensation for its successful conclusion”.

To employ a fragment 2-18 of SEQ ID NO: 1 of the instant invention as a diagnostic tool, which evidences a particular meaningful link to Alzheimer's disease, would clearly be using it as the object of further research, which has been determined by the courts to be a utility, which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for the claimed peptide in their currently available form, then the instant invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

(10) Response to Argument

At p. 10 of the Brief, Appellant submits that the instant specification discloses "an invention that is useful to the public as disclosed in its current form, rather than at some future date after further research, as a peptide marker linked to Alzheimer's disease". Appellant further reviews the case law pertained to the utility under 35 U.S.C. 101, and the appropriate sections of MPEP (pp. 10-12, 14-15 and 17-19 of the Brief). Appellant's review of the issue of utility, the

case law that has been cited and the holding that is found in that case law is not disputed. The only point of disagreement appears to be the interpretation of what constitutes a specific, substantial and credible utility.

At p. 10 of the Brief, Appellant argues that “the Examiner should presume that the claimed peptide (amino acid residues 2-18 of SEQ ID NO: 1) is useful as a marker for Alzheimer’s disease based upon Applicants’ showing in Figure 1 that the peptide is linked to Alzheimer’s disease by its differential expression in Alzheimer’s disease patients as compared to age-matched control patients”. The Examiner disagrees.

The currently claimed peptide 2-18 of SEQ ID NO: 1 is a fourteen amino acid long fragment of a peptide, which is nineteen amino acids long (see Sequence Listing of 03/12/2002) and which itself is a fragment of a longer full-length naturally occurring protein molecule. The evidence that peptide 2-18 of SEQ ID NO: 1 is not presented in Figure 1 can be found within the Figure 1 as well as within the text of the instant specification, as filed.

Specifically, “Figure 1 is a photograph of a tricine gel DEAE 3 (Elution) comparing Alzheimers disease versus Age Matched Control”, see p. 37 of the instant specification. The gel electrophoresis technique is one of the old staple tools in molecular biology, which allows identification of molecules by the band pattern according to their molecular weight. It is clear that the bands presented in Figure 1 cannot possibly represent a peptide 2-18 of SEQ ID NO: 1 itself, which is only fourteen amino acids long and has a molecular weight of about 1873 dalton (see p. 46 of the instant specification), and, therefore, cannot be seen within a gel where “high molecular weight standards” (see the box) were used. Further, the instant specification specifically states that “[I]n the instantly disclosed invention, we deal with proteins having a

molecular weight of about 20 kD or. In general, proteins of greater than 20 kD can reliably be fragmented by trypsin or other enzymes. [...] Proteins differ from peptides in that they cannot be effectively resolved by time flight MS and they are too large (>3kD) to be effectively fragmented by collision with gases. [...] Once the proteins have been resolved and visualized with stains the proteins that differ between disease states can then be excised from the gel and the protein purified in the 1-D gel band or 2-D gel spot can be cleaved into fragments less than 3kD by proteolytic enzymes" (pp. 36-37). Moreover, Appellant's own explanation of the technique used to isolate the instant claimed peptide confirms that "proteins, as collected from a serum sample, are too large to be effectively resolved by mass spectrometry and thus, are often first subjected to separation by polyacrylamide gel electrophoresis. Upon electrophoresis, the proteins contained in the sample separate into bands in specific areas of the gel according to weight and charge. The separate protein bands which are observed and deemed to be different between two comparable states (for example, disease vs. normal state) are excised from the gel and subjected to further fragmentation by enzymes", emphasis added (pp. 11-12 of the Brief).

Thus, Figure 1 relates to stage III of the protocol as presented at p. 12 of the Brief, where the raw mixture of proteins from the samples collected from four patients suspected of having Alzheimer's disease, four age-matched control and one normal control of pooled serum, was separated according to the molecular weight and charge within the gel. The instant claimed peptide 2-18 of SEQ ID NO: 1 is present within the band only in so far as it is a part of a larger naturally occurring molecule of a protein present within the bands. As stated at p. 13 of the Brief, only during artificial digestion ("fragmentation", see stage V at p. 13 of the Brief), fragment 2-18

of SEQ ID NO: 1 was “elucidated and identified” as being found “differentially expressed” between age-matched control patients and Alzheimer’s patients.

The instant specification discloses a peptide 2-18 of SEQ D NO: 1 and asserts its practical utility as “biopolymer marker which evidences a link to Alzheimer’s disease”. Appellant submits that the peptide could be used “to test the unknown sample for a link to Alzheimer’s disease through comparison of expression patterns, thereby demonstrating that the specification discloses a specific and substantial utility for the claimed peptide” (p. 13 of the Brief). However, the instant specification fails to teach what constitutes “a link to Alzheimer’s” and how to use the instant claimed peptide to make “the evidence” assessment.

The current law requires that utility must be disclosed to satisfy the section 112 enablement requirement. “[T]he how to use prong of section 112 incorporates as a matter of law the requirement of 35 U.S.C. §101 that the specification disclose as a matter of fact a practical utility for the invention.” *In re Cortright*, 165 F.3d 1353, 1356 [49 USPQ2d 1464] (Fed. Cir. 1999), quoting *In re Ziegler*, 992 F.2d 1197, 1200 [26 USPQ2d 1600] (Fed. Cir. 1993); *see also In re Schoenwald*, 964 F.2d 1122, 1124 [22 USPQ2d 1671] (Fed. Cir. 1992) (stating that utility must be disclosed to satisfy the section 112 enablement requirement). In explaining what constitutes a sufficient showing of utility in the context of the enablement requirement, this court has stated that an applicant's failure to disclose how to use an invention may support a rejection under either section 112, paragraph 1 for lack of enablement, or “section 101 for lack of utility ‘when there is a complete absence of data supporting the statements which set forth the desired results of the claimed invention.’” *Cortright*, 165 F.3d at 1356, quoting *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 762 [221 USPQ 473] (Fed. Cir. 1984).

In the instant case, Appellant claims a novel peptide asserted to be useful as Alzheimer's disease marker; however, there is no disclosure of the significance of finding of the peptide 2-18 of SEQ ID NO: 1 in a sample obtained from a patient. For example, if a fragment 2-18 of SEQ ID NO: 1 was found in a sample, what would that mean to the skilled practitioner? Is it a diagnosis of the absence of Alzheimer's disease, or is it evidence that the patient has a link to Alzheimer's disease, and if such, what does this link represent? The instant specification does not teach finding of the instant claimed peptide 2-18 of SEQ ID NO: 1 in any sample, the only information disclosed is limited to purification of a larger protein, which has a structural identity of fourteen common amino acids with the instant claimed peptide. There is also no evidence of record that this peptide 2-18 of SEQ ID NO: 1 is a naturally occurring fragment that can be easily identified or measured.

Appellant argues that "an applicant is not required to provide evidence of an asserted utility as a matter of statistical certainty" and that "providing an amount of the claimed marker that is diagnostic for Alzheimer's disease is not necessary to establish credibility of the asserted use for the claimed peptide as a marker for Alzheimer's disease" (p. 14 of the Brief). However, in the instant case, the only information available in the instant specification, as filed, is limited to disclosure of the structure of the peptide of SEQ ID NO: 1 and a vague indication that the peptide "is present/absent in disease vs. control" (p. 46 of the specification), and no further explanation or guidance for a skilled practitioner as to what represents the "link to Alzheimer's".

It is important to point out that the photographs of the gels as presented in Figures 1, 3 and 5 did not allow the Examiner to distinguish between the bands marked as AD and "Age matched control", as there appears to be no visible difference in the presence or absence of any

of the specific band type. The instant specification fails to specifically point out if the peptide 2-18 of SEQ ID NO: 1 was present or absent in samples related to AD (see description of figures at p. 46-47). The first Declaration of Ferris Landis under 37 CFR 1.132 filed June 09, 2003, states that the marker 2-18 of SEQ ID NO: 1 (ion 1873 dalton marker) is not present in normal sera (see sections 2, 3 and the MS spectra graph depicting ion 1873 attached to the Declaration); however, the third Declaration of Ferris Landis under 37 CFR 1.132 filed on February 09, 2006, states the opposite, that “band C1 [peptide 2-18 of SEQ ID NO: 1] is absent from lanes 1-4, which contain samples obtained from patients having Alzheimer’s disease” (see section 4). In the Brief, Appellant submits that it is the absence of the marker evidences the link to Alzheimer’s disease.

The Examiner disagrees that “[t]he identification of the presence of the claimed peptide in age-matched control patients and the absence (of the claimed peptide) in Alzheimer’s disease puts a researcher one step closer to understanding the pathogenesis of Alzheimer’s disease and, thus, also one step closer to improved diagnosis and treatment of Alzheimer’s disease” (p. 16 of the Brief). The Examiner maintains that the instant specification describes the peptide 2-18 of SEQ ID NO: 1 but discloses no utilities based on the detection of the peptide. The instant specification presents no factual evidence or sound scientific reasoning to support a conclusion that a peptide 2-18 of SEQ ID NO: 1 is specifically associated with pathogenesis of Alzheimer’s disease or involved in a particular physiological process leading to AD.

The U.S. Court of Appeals for the Federal Circuit recently addressed the utility requirement in the context of a claim to DNA. *See In re Fisher*, 2005 WL 2139421 (Sept. 7, 2005). The *Fisher* court interpreted *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (1966), as

rejecting a “de minimis view of utility” 2005 WL 2139421, at *4. The *Fisher* court held that § 101 requires a utility that is both substantial and specific. *Id.* At *5. The court held that disclosing a substantial utility means “show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some future date after further research. Simply put, to satisfy the ‘substantial’ utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public.” *Id.*

The court held that a specific utility is “a use which is not so vague as to be meaningless.” *Id.* In other words, “in addition to providing a ‘substantial’ utility, an asserted use must show that the claimed invention can be used to provide a well-defined and particular benefit to the public.” *Id.*

Just as in *Fisher* case where the Board reasoned that use of the claimed ESTs for the identification of polymorphisms is not a specific and substantial utility because “[w]ithout knowing any further information in regard to the gene represented by an EST, as here, detection of the presence or absence of a polymorphism provides the barest information in regard to genetic heritage,” (*Id.*, slip op. at 15), in the instant case, the detection of the peptide 2-18 of SEQ ID NO: 1 in a sample obtained from a subject provides no meaningful information with respect to diagnosis or treatment of Alzheimer’s disease, as asserted by Appellant.

Appellant submits that unlike to the invention of Fisher, “the claimed peptide is disclosed as a marker of a specific disease condition” (middle at . 19 of the Brief). However, the evidence of record is inadequate to support such conclusion because there is no evidence of record to show that peptide 2-18 of SEQ ID NO: 1 is a marker of Alzheimer’s disease. It is noted that Appellant uses terms “marker which evidences a link to Alzheimer’s disease” and “biopolymer marker of

“Alzheimer’s disease” interchangeably. However, since the instant specification fails to particularly point out what constitutes “a link to Alzheimer’s disease”, the presence of this limitation in the claim almost raises to the level of indefinite language for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At pp. 20-21 of the Brief, Appellant argues that “it is improper for Office personnel to merely question operability [of the invention]”. Appellant submits that “the Examiner requires Applicant to provide complete characterization of the claimed peptide, including data indicating what amount of the claimed peptide is diagnostic of Alzheimer’s disease, to establish a utility for the claimed peptide”. Appellant cites *Cortright* and states “that there is no *per se* requirement for clinical evidence to establish the utility of any invention”. However, Appellant mischaracterizes the Examiner’s position. The Examiner has never required provide a complete characterization of the claimed peptide, nor to present clinical evidence to establish the utility of the claimed peptide as a marker of (or an evidencer of a link to) Alzheimer’s disease. The only question with respect to the use of the instant claimed peptide 2-18 of SEQ ID NO: 1 that was asked by the Examiner was, what is the significance of finding this peptide in a sample? Since the instant specification fails to provide any evidence that the instant claimed peptide is a marker for Alzheimer’s disease, and it is not obvious what link to Alzheimer’s disease could become evident by finding the peptide 2-18 of SEQ ID NO: 1 in a sample, then the claimed invention is not patentable for not being useful in currently available form.

In *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), the court specifically stated that “a patent is not a hunting license”, “[i]t is not a reward for the search, but compensation for its successful conclusion”. The court expressed the opinion that all chemical compounds are

“useful” as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed “real world” utility. In the instant case the claimed peptide 2-18 of SEQ ID NO: 1 is only useful for further research to establish it’s specific and substantial utility.

To grant Applicant a patent encompassing an isolated fragment of a naturally occurring human protein, which is not readily usable in it’s current form, would be to grant Applicant a monopoly “the metes and bounds” of which “are not capable of precise delineation”. That monopoly “may engross a vast, unknown, and perhaps unknowable area” and “confer power to block off whole areas of scientific development, without compensating benefit to the public” (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966). To grant Applicant a patent on the claimed peptide based solely upon an assertion that the protein is linked to Alzheimer’s disease is clearly prohibited by this judicial precedent since the compensation to the public is not commensurate with the monopoly granted.

Thus, since the instant specification does not disclose a credible “real world” use for the isolated fragment 2-18 of SEQ ID NO: 1 in currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Further, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

For the above reasons, it is believed that the rejections should be sustained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

Respectfully submitted,



Olga N. Chernyshev, Ph.D.

Primary Examiner

Conferees:

Janet Andres, Ph.D.

Supervisory Patent Examiner, AU 1649



JANET L. ANDRES
SUPERVISORY PATENT EXAMINER

Gary Nickol, Ph.D.

Supervisory Patent Examiner, AU 1646



GARY B. NICKOL, PH.D.

SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600